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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

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02/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,524	JAWORSKI ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on December 19, 2008 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1-2 and 8-11 are pending.

Applicants' amendments filed December 19, 2008 is acknowledged. Applicant's response has been fully considered. Claim 1 has been amended. Therefore, claims 1-2 and 8-11 are examined.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2 and 8-11 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2 and 8-11 are directed to a polypeptide having elongase 3-ketoacyl CoA synthase (KCS) activity and comprising in the amino-terminal to carboxy-terminal direction: a first polypeptide segment having membrane anchoring properties; joined to a second polypeptide segment having a sequence of residues 75-114 of SEQ ID NO:12 or 14; joined to a third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The specification indicates the present invention provides polypeptide with altered elongase KCS (3-ketoacyl CoA synthase) substrate specificity and/or catalytic activity such as the peptides comprises three polypeptide segments, the amino-terminal first polypeptide segment having membrane anchoring properties, joined to a second polypeptide segment having a sequence of residues 75-114 of SEQ ID NO:12 or 14, followed by a third polypeptide segment having at least 40% sequence identity to the C-terminal 392 amino acids of SEQ ID NO:4 (residues 115-506), examples of such polypeptides have the sequences of SEQ ID NO:12 and 14 (page 3, lines 8-18; page 12, lines 5-9), where residues 115-506 of SEQ ID NO:12 and 14 having

>99% sequence identity to the residues 115-506 of SEQ ID NO:4, and the substrate specificity (C22:1/C20:1) of SEQ ID NO:12 or 14 resembles that of the wild-type Bn polypeptide (SEQ ID NO:4, Example 3; Tables 4 and 5). The specification further indicates the Bn G307D polypeptide had a higher elongase activity and produced more C22:1 product than the unmodified wild-type Bn polypeptide (SEQ ID NO:4; Example 4; Table 7). While species of the even numbered sequences in SEQ ID NO:8-42 (18 sequences) containing motifs or residues such as GNTSSSS (at positions 423-429 of SEQ ID NO:4), HAGG(R/K)A (at positions 391-396 of SEQ ID NO:4), MGCSAG (at positions 221-226 of SEQ ID NO:4) and/or G307D have been disclosed, the specification does not describe a genus of variants for the third polypeptide segment having at least 40% sequence identity to SEQ ID NO:4, when the structure to function/activity correlation is not indicated, and there is substantial variation in the whole genus. Without guidance on the correlation of structure to function/activity of the third polypeptide segment variants, one skilled in the art would not know which residues of the sequence are essential for function/activity. The lack of description on the structure to function/activity correlation of the third polypeptide segment variants, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate that the specification discloses how to determine percent sequence identity (see page 10, line 18 through page 11, line 25). Applicants' specification also discloses embodiments of the third polypeptide segment having particular residues or sequence motifs

(see, for example, page 12, lines 4-23). In addition, Applicants provide *eighteen* different examples of polypeptides that have a third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4. The sequence identity for these eighteen different sequences ranges from 54% up to 100% relative to residues 115-506 of SEQ ID NO:4 (See the even numbered sequences shown in SEQ ID NOs: 8-42). Based on this, the specification provides adequate written description for the third polypeptide segment. Furthermore, claim 1 has been amended to recite the functionality of the entire polypeptide. With respect to the individual polypeptide segment, the third polypeptide segment itself is not associated with a necessary functionality but can contain a number of conserved residues (see page 9, line 16- page 10, line 17; page 11, line 26-page 12, line 23). Applicants also indicate the structural limitations are not a requirement of written description but are one way by which written description can be demonstrated, thus, it would be improper for the Examiner to maintain the written description simply based on the lack of structure –function relationship with respect to the third polypeptide segment. In view of the remarks, the rejection should be withdrawn (pages 3-4 of the response).

Applicants' response has been fully considered, however, the arguments are not persuasive because of the following reasons. While the specification discloses all *eighteen* polypeptides (i.e., the even numbered sequences in SEQ ID NO:8-42) contain conserved motifs or residues such as GNTSSSS (at positions 423-429 of SEQ ID NO:4), HAGG(R/K)A (at positions 391-396 of SEQ ID NO:4), MGCSAG (at positions 221-226 of SEQ ID NO:4) and/or specific mutation G307D, the whole genus of the third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4 would contain numerous peptides, in which there are substantial structural variations. For example, out of 392 amino acid residues of

SEQ ID NO:4 (residues 115-506), 235 amino acid residues at any position can be varied (for 40% sequence homology), and each amino acid can be substituted with at least other 19 L-amino acids, which would result in as many as 20^{235} third polypeptide segments. Since there is no structure to function/activity correlation for the peptide variants of residues 115-506 of SEQ ID NO:4 shown, and the whole genus of third polypeptide variants would contain numerous sequences (e.g., 20^{235} third polypeptide segments), one skilled in the art would not know which third polypeptide variant of residues 115-506 of SEQ ID NO:4 is proper for the whole polypeptide having KCS activity. Although structural limitation is not the only way to demonstrate the written description, there are no other characteristics identified for the third polypeptide segment variants, thus, the specification does not provide sufficient written description for the genus of third polypeptide segment variants. While some conserved motifs or residues (e.g., page 12, lines 4-23 of the specification) are indicated in the variants of third polypeptide segment, these motifs are not cited in the claims, thus the whole genus of third polypeptide segments contains numerous embodiments with substantial structural variations. Therefore, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Conclusion

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
February 11, 2009